#### PATENT APPLICATION

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Docket No: Q88366

Hiroshi HORIUCHI, et al.

Appln. No.: 10/537,493

Group Art Unit: 1781

Confirmation No.: 4639

Examiner: Hamid R. Badr

Filed: June 3, 2005

For:

METHOD FOR PRODUCING FERMENTED MILK AND FERMENTED MILK

#### SUBMISSION OF APPEAL BRIEF

#### MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The USPTO is directed and authorized to charge the statutory fee of \$540.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

	Respectfully submitted, /Sunhee Lee/
SUGHRUE MION, PLLC Telephone: (202) 293-7060 Facsimile: (202) 293-7860	Sunhee Lee Registration No. 53,892
WASHINGTON DC SUGHRUE/265550 65565	/Yan Lan/
CUSTOMER NUMBER  Date: May 18, 2010	Yan Lan Registration No. 50,214

# PATENT APPLICATION

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METHOD FOR PRODUCING FERMENTED MILK AND FERMENTED MILK

## APPEAL BRIEF UNDER 37 C.F.R. § 41.37

## MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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# I. REAL PARTY IN INTEREST

The real party interest is MEIJI DAIRIES CORPORATION, by virtue of an assignment recorded by the PTO on June 3, 2005, at Reel 017122, at Frame 0176.

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# II. RELATED APPEALS AND INTERFERENCES

To the knowledge and belief of Appellants, the Assignee, and the undersigned, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be affected by the Board's decision in the instant Appeal.

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# III. STATUS OF CLAIMS

Claims 5, 6, 8-12, 14 and 15 are pending.

Claims 1-4, 7 and 13 are canceled.

Claims 5, 6, 8-12, 14 and 15 are rejected, and are the subject of this appeal.

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# STATUS OF AMENDMENTS

No amendment was filed subsequent to the final Office Action dated January 6, 2010.

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# V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 5 and 10 are the only independent claims on appeal.

Independent claim 5 is directed to a method for producing fermented milk. *See* page 6, lines 22-23. The method comprising the steps of: reducing the concentration of dissolved oxygen in a mixture comprising milk at the start of fermentation to 5 ppm or less by substituting the dissolved oxygen with an inert gas; and carrying out fermentation at a fermentation temperature of from 30°C to 37°C. The method recited in claim 5 is described in the present specification, e.g., at least on page 8, lines 5-12, page 9, lines 7-20, and page 11, lines 10-11. The inert gas is selected from the group of nitrogen, argon, and helium gas. *See* page 9, lines 24-26.

Independent claim 10 is directed to a fermented milk. *See* page 12, lines 1-4. The fermented milk has a penetration angle of 31° or less and a hardness of 40 g or more, and the hardness is an elasticity until break of the penetration angle curve obtained by a measurement of the penetration angle of a yogurt knife with a weight of 100 g using a neocurd meter. The penetration angle is an indicator of smoothness. The physical properties of the fermented milk according to the present invention and the fermented milk recited in claim 10 are described in the present specification, e.g., at least in Table 1 of page 16.

Although the above summary refers to portions of the specification, these references should not be considered to be limiting. Rather, they reflect examples of the disclosed exemplary embodiments.

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# VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

claims 5-6 and 8-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Castberg et al. (U.S. Patent No. 5,453,256 (sic, 5,453,286); hereinafter R1) in view of Kamiya (EP 1 082 907; hereinafter R2).

Claims 5-6, 8-12 and 14-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Castberg et al. (R1) in view of WO-02248470 (hereinafter R3).

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#### VII. ARGUMENT

A. The rejection of claims 5-6 and 8-13 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Castberg et al. U.S. Patent No. 5,453,256 (sic, U.S. Patent No. 5,453,286); hereinafter R1) in view of Kamiya (EP 1 082 907; hereinafter R2) should be reversed because a *prima facie* case of obviousness has not been established.

Independent claim 5 of the present invention recites:

A method for producing fermented milk, which comprises reducing the concentration of dissolved oxygen in a mixture comprising milk at the start of fermentation to 5 ppm or less by substituting the dissolved oxygen with an inert gas selected from the group of nitrogen, argon, or helium gas; and carrying out fermentation at a fermentation temperature of from 30°C to 37°C.

Independent claim 10 of the present invention recites:

A fermented milk, which has a penetration angle of 31° or less and a hardness of 40 g or more, wherein the hardness is an elasticity until break of the penetration angle curve obtained by a measurement of the penetration angle of a yogurt knife with a weight of 100 g using a neocurd meter, and the penetration angle is an indicator of smoothness.

The Examiner admits that R1 fails to teach the dissolved oxygen concentration in the milk at the time of start of fermentation and fails to teach the claimed step of substituting the dissolved oxygen with an inert gas to reach the recited concentration of dissolved oxygen. *See* Office Action dated January 6, 2010, page 4, paragraph 12.

The Examiner relies on R2 as teaching the replacement of dissolved oxygen with N<sub>2</sub>.

Regarding the claimed fermented milk of claim 10, the Examiner asserts that the method as disclosed by R1 and R2 would intrinsically result in fermented milk with penetration angle

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and hardness as presently claimed. See Office Action dated January 6, 2010, page 5, and

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paragraph 15.

Error in the Reasoning of the Office Action

A fundamental issue in the present § 103 rejection is that the Examiner takes the position that it would have been obvious to one of ordinary skill in the art to modify R1 and adopt the teachings of R2, to replace the CO<sub>2</sub> used in R1 process with N<sub>2</sub> of R2 to reduce the dissolved oxygen in the milk medium to accelerate the growth of the starter culture, and hence reduce the incubation time as presently claimed.

Appellants respectfully traverse the Examiner's position.

(1) A mere fact that the references disclose that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

In the present case, there is no objective reason to combine the teachings of R1 and R2 to modify the process of R1, because such modification of R1 would render the invention of R1 being modified unsatisfactory for its intended purpose. MPEP 2143.01 (V) states that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

R1 teaches a method of converting milk or pasteurized milk into a fermented milk, which comprises high-temperature heat treatment of milk or pasteurized milk, followed by carbonation of the heat-treated milk with CO<sub>2</sub> gas, and starter culture is added to the carbonated milk. R1

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specifically requires CO<sub>2</sub> gas continuously present in the milk (col. 4, lines 34-47) during fermentation and emphasizes the importance thereof in terms of volatile aroma compounds (col. 6, lines 43-62), balance and total viable counts of useful bacteria (col. 6, line 63-col. 7, line 5), sensory evaluation, and firmness of the produced yogurt. *See also*, Examples of R1. What R1 teaches is <u>not</u> to reduce O<sub>2</sub> concentration, but add and maintain CO<sub>2</sub> gas consistently throughout the fermentation process.

Therefore, one skilled in the art would not have been motivated to remove  $CO_2$  from the process of R1 and replace  $CO_2$  of R1 with other gases, because the process of R1 specifically requires the *continuous presence of saturated CO\_2 gas in the milk* during fermentation to attain its desired goal. It is crystal clear that there is no motivation or suggestion for one skilled in the art to remove or replace  $CO_2$  used in R1 process with  $N_2$  used in the R2 process.

(2) Further, because the problems to be solved and the solutions provided by R1 and R2 are different, there is no objective reason to combine the teachings of R1 and R2.

The object in R1 is to add CO<sub>2</sub> is to produce and maintain volatile aroma components during fermentation. It is noted that R1 also teaches shortening the incubation time during production of a fermented milk. However, the solution for shortening the incubation time, suggested by R1, is to subject milk to high-temperature heat treatment or pasteurization, before adding CO<sub>2</sub> gas. Col. 3, lines 34-36 and col. 3, lines 55-60.

Therefore, the Examiner's assertion that one skilled in the art would have been motivated to replace CO<sub>2</sub> in R1 process with N<sub>2</sub> as taught in R2 is flawed and is lacking merits.

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(3) Furthermore, it is noted that in R2, the substitution of the dissolved oxygen with nitrogen gas is carried out before pasteurization of raw milk (which occurs before starting fermentation).. See Paragraph [0019]. R2 requires the N<sub>2</sub> gas to be added before sterilization.

Therefore, even if R1 and R2 are combined, the combined teachings do not teach each and every element as defined in the claims of the instant application, because neither of R1 or R2 teaches that the dissolved oxygen be reduced to a certain amount when the fermentation starts, as recited in claim 1.

Appellant further respectfully submits that neither R1 or R2 discloses or teaches varying the timing of the CO2 addition or N2 substitution to reduce the dissolved oxygen concentration to a certain level, at the time when the fermentation is started, as required by the present claims.

The Examiner has failed to articulate why the superior results of the present invention would have been predictable to one of ordinary skill in the art in view of the teachings of R1 and R2.

Appellants respectfully submitted that, for at least the reasons discussed above, there is no motivation to combine the asserted teachings of R1 and R2. Therefore, the Examiner's assertion that the method as disclosed by R1 and R2 would intrinsically result in fermented milk with the penetration angle and hardness as presently claimed, lacks merit. Accordingly, the rejection of claim 10 as being unpatentable over the teachings of R1 and R2 should be reversed.

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B. The rejection of Claims 5-6, 8-12 and 14-15 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Castberg (R1) in view of WO-02248470 (hereinafter R3) should be reversed because a *prima facie* case of obviousness has not been established.

A *prima facie* showing of obviousness requires a teaching or suggestion of all claimed limitations.

The Examiner admits that R1 is silent as to the dissolved oxygen concentration and how it can be monitored using an inert gas. The Examiner relies on R3 to teach this feature of claims 5-6, 8-12 and 14-15.

Regarding the claimed fermented milk of claim 10, the Examiner asserts that the method as disclosed by R1 and R3 would intrinsically result in fermented milk with penetration angle and hardness as presently claimed. *See* Office Action dated January 6, 2010, page 8, and paragraph 30.

Appellants respectfully disagree.

R3 does not make up for the noted deficiency of R 1. R3 is silent as to a dissolved oxygen concentration, as recited in instant claim 5.

R3 is directed to a ferment activator based on lactic acid bacteria and method for preparing a dairy product using such activator. The ferment activator comprises a nitrogenous substance and a buffer system capable of maintaining the activity pH of the lactic acid bacteria with which said activator is to be associated at a value ranging between 5 and 7, and free of added sugar(s) capable of being metabolized by said lactic acid bacteria. (See Abstract). Step (i) of preparing a milk product requires bringing of the ferment into contact with the claimed activator in a sealed reservoir. The temperature of the aqueous medium on its arrival in the

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sealed reservoir is between 50°C and 15°C, preferably between 8°C and 12°C. An internal stirring system is inside the sealed reservoir and the stirring allows the suspension of the ferments and of the activator in the aqueous medium. A gas is advantageously used which is not involved in respiration and/or oxidation in the microorganisms, the ferments and the bacteria. The injected gas is a chemically and biologically inert gas, preferably argon, more particularly nitrogen or carbon dioxide. (See column 4, paragraphs [0075] - [0083]).

However, R3 is silent as to a dissolved oxygen concentration as recited in instant claim 1. R3 fails to cure the deficiency of R1. There is no teaching or suggestion within the either one of the cited references R1 and R3 for a specific range of the concentration of dissolved oxygen to be 5 ppm or less of, except from an impermissible hindsight reconstruction of Applicants' invention, using Applicants' claims as template.

Accordingly, a *prima facie* case of obviousness has not been established.

Appellants respectfully submitted that, for at least the reasons discussed above, there is no motivation to combine the asserted teachings of R1 and R3. Even if, *arguendo*, the references were somehow combined, the asserted combination of R1 and R3 fails to disclose or teach the claimed method for producing fermented milk according to the present invention. Therefore, the Examiner's assertion that the method as disclosed by R1 and R3 would intrinsically result in fermented milk with penetration angle and hardness as presently claimed, lacks merits. The instantly claimed fermented milk of claim 10 are patentable in view of the teachings of R1 and R3.

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C. The Claimed Method Shows Unexpectedly Superior Effects

Further, the superior results of the present invention would not have been predictable to

one of ordinary skill in the art in view of the teachings of R1 and R2 or R3.

As shown in the executed Declaration by Mr. Horiuchi, which was submitted on June 17,

2009, and entered into the record by the Examiner, the claimed method shows unexpected results

for producing fermented milk with superior properties.

As can be seen in the Rule 132 Declaration, one Additional Experiment and one

Additional Comparative Experiment were prepared. The Additional Experiment was conducted

under the conditions according to the present invention, and in particular, the oxygen was

substituted with nitrogen. The Additional Comparative Experiment was conducted in the same

manner as the Additional Experiment, except that carbon dioxide was used instead of nitrogen to

substitute the oxygen. The organoleptic properties of the fermented products of the Additional

Experiment and Additional Comparative Experiment were measured and compared. The Rule

132 Declaration shows the unexpected effects of the invention in commensurate with the scope

of the claimed subject matter.

Conclusion

For at least the above reasons, Appellants submit that the Examiner has failed to establish

a prima facie case of obviousness. Thus, the present claims 5, 6, 8-12, 14 and 15 are patentable

over R1 in view of R2 or R3. Accordingly, Appellants respectfully request reversal of all the

§103(a) rejections.

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The USPTO is directed and authorized to charge the fee required under 37 C.F.R. § 41.37(a) and 1.17(c), and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

	Respectfully submitted,
SUGHRUE MION, PLLC	/Sunhee Lee/
Telephone: (202) 293-7060 Facsimile: (202) 293-7860	Sunhee Lee Registration No. 53,892
WASHINGTON DC SUGHRUE/265550 65565 CUSTOMER NUMBER	/Yan Lan/
	Yan Lan
Date: May 18, 2010	Registration No. 50,214

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### **CLAIMS APPENDIX**

#### CLAIMS 5, 6, 8-12, 14 and 15 ON APPEAL:

5. A method for producing fermented milk, which comprises

reducing the concentration of dissolved oxygen in a mixture comprising milk at the start of fermentation to 5 ppm or less by substituting the dissolved oxygen with an inert gas selected from the group of nitrogen, argon, or helium gas; and

carrying out fermentation at a fermentation temperature of from 30°C to 37°C.

- 6. The method for producing fermented milk according to claim 5, wherein the period of carrying out fermentation is shorter than a period of carrying out fermentation without reducing the concentration of dissolved oxygen at the fermentation temperature.
  - 8. The fermented milk produced by the method according to claim 5.
  - 9. The fermented milk produced by the method according to claim 6.
- 10. A fermented milk, which has a penetration angle of 31° or less and a hardness of 40 g or more, wherein the hardness is an elasticity until break of the penetration angle curve obtained by a measurement of the penetration angle of a yogurt knife with a weight of 100 g using a neocurd meter, and the penetration angle is an indicator of smoothness.
- 11. The fermented milk produced by the method according to claim 5, which has a penetration angle of 31° or less and a hardness of 40 g or more, wherein the hardness is an elasticity until break of the penetration angle curve obtained by a measurement of the penetration angle of a yogurt knife with a weight of 100 g using a neocurd meter, and the penetration angle is an indicator of smoothness.

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12. The fermented milk produced by the method according to claim 6, which has a penetration angle of 31° or less and a hardness of 40 g or more, wherein the hardness is an elasticity until break of the penetration angle curve obtained by a measurement of the penetration angle of a yogurt knife with a weight of 100 g using a neocurd meter, and the penetration angle is an indicator of smoothness.

- 14. The method for producing fermented milk according to claim 5, wherein the inert gas in nitrogen.
- 15. The method for producing fermented milk according to claim 5, further comprising subjecting the mixture to sterilization, prior to the step of reducing the concentration of dissolved oxygen in the mixture,

wherein the sterilization, reducing the concentration of dissolved oxygen, and fermentation are carried out in this order.

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# **EVIDENCE APPENDIX:**

Pursuant to 37 C.F.R. § 41.37(c)(1)(ix), submitted herewith are copies of any evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the Examiner and relied upon by Appellant in the appeal.

1. Appellants submit herewith a copy of Mr. Hiroshi Horiuchi's Declaration under 37 C.F.R. § 1.132, previously submitted on June 17, 2009, and entered by the Examiner.

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# RELATED PROCEEDINGS APPENDIX

Submitted herewith are copies of decisions rendered by a court or the Board in any proceeding identified about in Section II pursuant to 37 C.F.R. § 41.37(c)(1)(ii).

None.

#### PATENT APPLICATION

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q88366

Hiroshi HORIUCHI, et al.

Appln, No.: 10/537,493

Group Art Unit: 1794

Confirmation No.: 4639

Examiner: Hamid R. Badr

Filed: June 3, 2005

For:

METHOD FOR PRODUCING FERMENTED MILK AND FERMENTED MILK

#### **DECLARATION UNDER 37 C.F.R. § 1.132**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Hiroshi Horiuchi, hereby declare and state:

THAT I am a citizen of Japan;

THAT I received a master's degree from Kyushu University, Faculty of Agriculture in March 1997;

THAT, I have been employed by MEIJI DAIRIES CORPORATION since April 1997, and assigned to Nishi Shunbetsu Plant to be engaged in manufacturing control of cheese, cream, butter, skimmed milk powder, etc; and

THAT, in March 1998, I was transferred to Food Development Research Institute, and since then, I have been engaged in development of yogurt.

In order to show unobviousness and unexpected effects of the claimed subject matter of the above-identified application over references cited in the Office Actions (i.e., Castberg

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et al. (US 5,453,256, "R1"), the following experiments were performed by me or under my supervision.

The following Additional Experiment according to the present invention (substitution with nitrogen) was conducted in order to show the unexpected effects of the invention in commensurate with the scope of the claimed subject matter.

# Additional Experiment According to the Present Invention (substitution with nitrogen)

A mix was prepared by mixing 78.2 kg of milk, 2.6 kg of powdery skim milk, and 17.2 kg of water. The mix was sterilized under heating at 95°C for 5 minutes, and cooled to 37°C. Subsequently, a lactic acid starter (a mix culture of *Lactobacillus bulgaricus (L. bulgaricus* JCM 1002T) and *Streptococcus thermophilus* (S. thermophilus AYCC 19258)) was inoculated at 2% by weight. Nitrogen gas was mixed and dispersed into the mix through a pipe, to adjust a dissolved oxygen concentration to about 2 ppm. Then, the mix was packed into a 100-ml container, for static fermentation in fermentation chamber at 37°C, until the lactic acid acidity reached around 0.7%. Just then, the resulting product was put in a refrigerator at 10°C or less, for cooling and termination of fermentation to prepare fermented milk. In this regard, the lactic acid acidity was calculated by the titration with 0.1 N NaOH by using phenolphthalein as an indicator.

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# Additional Comparative Experiment (substitution with carbon dioxide)

Additional Comparative Experiment was conducted in the same manner as in Additional Experiment according to the present invention described above, except that carbon dioxide was used instead of nitrogen. The dissolved oxygen concentration was adjusted to about 2 ppm, also as in Additional Example of the present invention.

In this regard, I would like to note that the start culture used in this Comparative Experiment is not identical to that used in Example IV of RI. This is because I believe that this Comparative Experiment conditions are closer to the conditions of the above Additional Experiment according to the present invention and thus is more suitable for comparison for proving unexpected results of the present invention.

#### Results

(1) Fermentation time (time required to reach lactic acid acidity of 0.7%)

Additional Experiment according to the present invention: 170 min (pH at the start of fermentation = 6.53, acidity = 0.19%)

Additional Comparative Experiment: 170 min (pH at the start of fermentation = 6.07, acidity = 0.30%)

At the finish of fermentation, pH was 4.80 and acidity was 0.70% in each of Additional Experiment according to the present invention and Additional Comparative Experiment.

(2) Curd tension (standard of hardness)

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Additional Experiment according to the present invention: 50.0 g

Additional Comparative Experiment: 48.5 g

(3) Penetration angle of curd knife (standard of smoothness)

Additional Experiment according to the present invention: 27°

Additional Comparative Experiment: 55°

As shown by the above data, when substitution with carbon dioxide was conducted as in Additional Comparative Experiment, it was not possible to produce fermented milk having sufficient smoothness.

### (4) Organoleptic assessment

Smoothness of the fermented milk of the Additional Experiment according to the present invention was more excellent than that of the fermented milk of Additional Comparative Experiment.

In addition, it was confirmed that the fermented milk of Additional Comparative Experiment gave a tartish taste which is considered to be derived from carbonic acid.

From the results obtained and compared above, I believe that the method for producing fermented milk and thus produced fermented milk, defined in the claims of the instant application, show unexpected results.

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I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: June 15, 2009

Mr. Hiroshi Horiuchi